IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	CIVIL ACTION NO. 99-20593
v.	)	
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9029

Bartle, J. March 21, 2013

Peggy A. Rogers ("Ms. Rogers" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Theodore P. Rogers, claimant's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In October, 2004, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Bassem Mikhail, M.D. Based on an echocardiogram dated September 22, 2004, Dr. Mikhail attested in Part II of claimant's Green Form that Ms. Rogers suffered from moderate mitral regurgitation and an abnormal left atrial dimension.[4] Based on such findings,

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3. (...continued)
presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. In addition, Dr. Mikhail attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition is not at issue in this claim.

claimant would be entitled to Matrix B-1,[5] Level II benefits in the amount of $83,178.[6]

In the report of claimant's echocardiogram, the reviewing cardiologist, John J. Bartolozzi, M.D., stated, "Moderate mitral regurgitation is present." Dr. Bartolozzi, however, did not specify a percentage as to the level of claimant's mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In July, 2005, the Trust forwarded the claim for review by Dai-Trang Elizabeth Le, M.D., one of its auditing cardiologists. In audit, Dr. Le concluded that there was no reasonable medical basis for Dr. Mikhail's finding that claimant

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5. In her Green Form, claimant requested benefits on Matrix A-1. Upon review of claimant's Green Form and supporting materials, the Trust determined, and claimant did not contest, that if eligible, Ms. Rogers would only receive benefits on Matrix B-1 because her March 27, 2003 echocardiogram demonstrated only mild mitral regurgitation. See Settlement Agreement § IV.B.2.d.(2)(a).

6. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). Although the Trust disputes that claimant had an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, we need not resolve this issue given our determination with respect to claimant's level of mitral regurgitation.

had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. Dr. Le explained that the "[q]uality of [the] [transthoracic echocardiogram] was too poor to allow for quantitative analysis. However, on color flow doppler and pulse wave, there was mild mitral regurgitation."

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination denying the claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[7] In contest, claimant argued that under the reasonable medical basis standard, the attesting physician's conclusions should be accepted unless they are "extreme or excessive" and constitute medical malpractice. Ms. Rogers further contended that "[q]uantifying the level of regurgitation shown on an echocardiogram is inherently subjective."[8] Claimant also submitted that the auditing cardiologist simply substituted her own opinion for that of the attesting physician and that the

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7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to this claim.

8. In support of this argument, claimant submitted excerpts of depositions of five (5) physicians from other proceedings. None of the testimony submitted by the claimant, however, addressed the claim of Ms. Rogers.

auditing cardiologist did not provide a measurement as to the level of claimant's mitral regurgitation. Finally, claimant argued there was a reasonable medical basis for Dr. Mikhail's finding of an abnormal left atrial dimension because Dr. Bartolozzi agreed with this determination.

The Trust then issued a final post-audit determination again denying the claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the claim should be paid. On February 28, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6028 (Feb. 28, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on September 8, 2006, and the claimant submitted a sur-reply on November 8, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[9] to review claims after the Trust and

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9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there (continued...)

claimant have had their opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. at Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Rogers reasserts the claims she made in contest. Claimant also contends that it is not uncommon for two cardiologists to review the same

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9. (...continued)
are conflicting expert opinions, a court may seek assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

echocardiogram and to find different levels of regurgitation, and as such, "[n]either diagnosis is correct or incorrect; both fall within the realm of having 'a reasonable medical basis.'" In further support of her claim, Ms. Rogers submitted a report from A.R. Maniet, D.O. In his report, Dr. Maniet stated that he reviewed claimant's echocardiogram and his measurement "yielded an area of the left atrium of 19.48 cm2 and an area of the mitral regurgitant jet of 4.32 cm2 corresponding to a RJA/LAA ratio of 22% or moderate mitral regurgitation." Dr. Maniet attached several still frames that purportedly demonstrate his findings.

In response, the Trust disputes claimant's characterization of the reasonable medical basis standard. The Trust also asserts that Dr. Maniet's opinion does not establish a reasonable medical basis for Dr. Mikhail's representation of moderate mitral regurgitation because it is based on the planimetry of an RJA from a single still frame and the jet in that still frame appears to be early in systole consistent with backflow. Finally, the Trust argues that Dr. Maniet does not identify a sustained, representative jet of mitral regurgitation that appears in multiple loops and several consecutive frames.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded there was no reasonable basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Vigilante explained:

I reviewed the Claimant's echocardiogram of Mach 27, 2003.... Although there was increased color gain on this study, I was able to assess the severity of mitral regurgitation. Visually, only mild mitral regurgitation was noted in the apical four chamber and apical two chamber views. I digitized those cardiac cycles in which the mitral regurgitation appeared most impressive in the apical four chamber and apical two chamber views. I then digitally traced and calculated the RJA and LAA. The LAA was 17.0 cm2 in the apical four chamber view. The largest representative RJA in the apical four chamber view was 2.2 cm2. The largest representative RJA in the apical two chamber view was 1.5 cm2. Therefore, the largest representative RJA/LAA ratio was less than 13% in the apical four chamber view. This ratio was less than 10% in the apical two chamber view. The RJA/LAA ratio never came close to approaching 20%.

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I reviewed the Claimant's echocardiogram of September 22, 2004.... This was a below average quality study with the usual echocardiographic views obtained.... Although there was increased color gain on this study, I was able to accurately determine the severity of mitral regurgitation.

... Visually, mild mitral regurgitation was noted. I digitized those cardiac cycles in the apical four chamber and apical two chamber views which the mitral regurgitation was best evaluated. I then digitally traced and calculated the RJA and LAA. I determined that the LAA was 17.7 cm2. The largest representative RJA in the apical four chamber view was 3.2 cm2. The largest RJA in the apical two chamber view was 2.6 cm2. These determinations were made in the mid portion of systole and were devoid of backflow or low velocity, non-mitral regurgitant flow. Therefore, the largest representative RJA/LAA ratio in the apical four chamber view was 18%. Continuous wave Doppler was evaluated on the study. This was a faint jet

> consistent with mild mitral regurgitation. The largest representative RJA/LAA ratio in the apical two chamber view was less than 15%. Most of the RJA/LAA ratios were less than 10%. The RJA/LAA ratio never reached 20%. I reviewed Dr. Maniet's screen shots as well as the time on the echocardiogram tape that these images were obtained. The supposed RJA of 4.32 cm2 noted on Dr. Maniet's screen shot was not representative of mitral regurgitation and contained a great deal of low velocity, non-mitral regurgitant flow. Therefore, his RJA measurement of 4.32 cm2 was inaccurate. I also reviewed Dr. Maniet's screen shot of the supposed LAA. His measurement of 18.48 cm2 was incorrect as it went beyond the inner border of the left atrium both laterally and along the interatrial septum. The correct LAA at this time frame on the echocardiogram tape was 17.7 cm2.

After reviewing the entire show cause record, we find claimant's arguments are without merit. As an initial matter, we disagree with claimant's characterization of the reasonable medical basis standard. We are required to apply the standards delineated in the Settlement Agreement and the Audit Rules. The context of these two documents leads us to interpret the reasonable medical basis standard as more stringent than claimant contends, and one that must be applied on a case-by-case basis.[10] Here, Dr. Le determined in audit, and Ms. Rogers does not adequately dispute, that there is no reasonable medical basis for the attesting physician's representation that claimant had

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10. For this reason as well, we reject claimant's assertion that an attesting physician's finding should always be accepted unless it constitutes medical malpractice.

moderate mitral regurgitation.[11] According to Dr. Le, the "[q]uality of [the transthoracic echocardiogram] was too poor to allow for quantitative analysis. However, on color flow doppler and pulse wave, there was mild mitral regurgitation." Contrary to claimant's argument, Dr. Le properly applied the reasonable medical basis standard under the Settlement Agreement.[12]

We also disagree with claimant that the opinion of Dr. Maniet provides a reasonable medical basis for Dr. Mikhail's representation that claimant has moderate mitral regurgitation. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow," and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount

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11. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

12. Thus, we find that this is not merely conflicting "subjective" diagnoses between the attesting physician and auditing cardiologist. Nor has Dr. Le substituted her opinion for that of the attesting physician. Instead, Dr. Le found that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation based on clearly identified deficiencies in the attesting physician's conclusion.

of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). Dr. Vigilante reviewed the tracings provided by Dr. Maniet and noted that the RJA measurement was inaccurate because it "was not representative of mitral regurgitation and contained a great deal of low velocity, non-mitral regurgitant flow." Dr. Vigilante also determined that Dr. Maniet's LAA measurement was incorrect because it "went beyond the inner border of the left atrium both laterally and along the interatrial septum." Such unacceptable practices cannot provide a reasonable medical basis for the resulting Green Form representation of moderate mitral regurgitation.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of the claim of Ms. Rogers for Matrix Benefits and the related derivative claim submitted by her spouse.